

## **REMARKS/ARGUMENTS**

### **The Claim Amendments**

The claims are amended herewith to eliminate the need for the added vegetable oil excipient. This issue was raised by the Examiner in statements in the outstanding Office action that bioavailability of the freeze-dried cyclodextrin/carotenoid complex was affected by the vegetable oil excipient. This statement/understanding is contrary to the data presented in the original patent application. Examples 1-4 that contain cell uptake data establishing the unexpected improvement in cell bioavailability is a property of the freeze-dried cyclodextrin/carotenoid complex without any excipient in general and without any vegetable oil specifically. As the Examiner may note by re-reading the working examples, Examples 6 and 7, which demonstrate human testing of the freeze-dried cyclodextrin/carotenoid complex, use the vegetable oil excipient; however, based on the cell uptake data in Examples 1-5, improved bioavailability is a property of the freeze-dried cyclodextrin/carotenoid complex itself. For completeness, Example 5 shows cellular uptake with 3 different excipients added to the complex. Only one of the excipients tested, however, preserved cellular uptake activity of the complex. The other two excipients lowered cellular uptake dramatically. The unpredictability of the complex again is demonstrated.

As such, Applicants believe that by leaving an extraneous ingredient as part of the claims defocuses attention on the subject matter that Applicants deem to be patentable and to which their invention is addressed. Thus, the amended claims are fully supported in the original specification. No new matter is added by virtue of these amendments and their entry respectfully is requested. These claim amendments were made necessary by the Examiner's statements in the outstanding Office action and, thus, are submitted to be timely.

### **The Claim Rejections**

#### **A. Claims 1, 5**

Claims 1 and 5 stand finally rejected under the provisions of 35 U.S.C. § 102(b) as being anticipated by Szente. Applicants' remarks submitted with July 3, 2006 amendment are incorporated herein by reference. Again, Szente teaches only 1 carotenoid complex and provides no teaching that complex drying technique affects cellular bioavailability. Szente simply is irrelevant to the current claims.

B. Claims 1, 5-7

Claims 1 and 5-7 stand finally rejected under the provisions of 35 U.S.C. § 102(b) as being anticipated by Basu. Applicants' remarks submitted with July 3, 2006 amendment are incorporated herein by reference. Again, Basu teaches a triglyceride oil complex having binary and ternary complexes with cyclodextrin. Basu simply is irrelevant to the current claims.

C. Claims 1, 5

Claims 1 and 5 stand finally rejected under the provisions of 35 U.S.C. § 103(a) as being unpatentable over Szente in view of Hedges. Applicants' remarks submitted with July 3, 2006 amendment are incorporated herein by reference. Again, Hedges adds nothing, but, perhaps, strengthening Applicants' position in that Hedges equates all forms of drying. As such, this combination fails to make obvious the current claims.

D. Claims 1, 6

Claims 1 and 6 stand finally rejected under the provisions of 35 U.S.C. § 103(a) as being unpatentable over Olmedilla in view of Pfitzner. Applicants' remarks submitted with July 3, 2006 amendment are incorporated herein by reference. Again, this combination fails to make obvious the current claims.

E. Claims 5 and 7

Claims 5 and 7 stand finally rejected under the provisions of 35 U.S.C. § 103(a) as being unpatentable over Olmedilla in view of Pfitzner in further view of Szente. Applicants' remarks submitted with July 3, 2006 amendment are incorporated herein by reference. Again, this combination fails to make obvious the current claims.

F. Claims 11, 15-17, 19

Claims 1-10 stand finally rejected under the provisions of 35 U.S.C. § 103(a) as being unpatentable over Olmedilla in view of Pfitzner, Sharper and Mele. Applicants' remarks submitted with July 3, 2006 amendment are incorporated herein by reference. Again, this combination fails to make obvious the current claims.

G. Copending Application USSN '999

While it still is Applicants' position that this is not available as a reference, the present invention clearly is patentable over the disclosure of this application. That is, the prior

application only enables spray drying and equates all forms of drying, including freeze-drying. Thus, there is no way that the inventors of the prior application could have known that freeze-drying would be so superior to the forms of drying. Data testifying to this fact has been presented and not rebutted. Thus, Applicants are at a loss to understand how the Examiner can maintain, "that no unexpected results, with respect to the instant claims, have yet been presented." The working examples in the present application do just that. See Table 1 from the application reproduced below.

TABLE 1  
Effect of Drying on the Uptake of Lutein from the  
Lutein/ $\gamma$ -Cyclodextrin Complex by Caco2 Cells

| Sample  | Cellular Lutein Uptake<br>(Percent Increase) |                  |
|---|--|------------------|
|   | 6-hr Incubation                              | 24-hr incubation |
| Spray-dried Lutein/ $\gamma$ -cyclodextrin Complex  | 8.75   | 14.35            |
| Freeze-dried Lutein/ $\gamma$ -cyclodextrin Complex | 20.5   | 56.1             |

These results demonstrate a 134% increase at 6 hours of the freeze-dried complex (neat, *i.e.*, without vegetable oil) over the spray-dried complex and a 291% increase in cell uptake of lutein of the freeze-dried complex (neat, *i.e.*, without vegetable oil) over the spray-dried complex. In the face of such data, the Examiner's position is untenable. No art, and particularly not USSN '999, gives the artisan any glimmer of such unexpected cellular uptake merely based on the method of recovery (drying) of the lutein complex product. It such unexpected cellular uptake that defines the invention over all of the art cited.

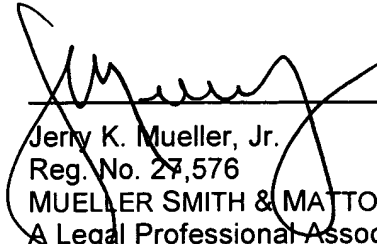
Thus, the present claims, then, are patentable over USSN '999.

#### H. Summary

In view of the remarks, previously submitted declarations, claim amendments, and the remarks herewith, allowance of all claims and passage to issue of this application respectfully is requested. If allowance is not forthcoming, please enter this amendment for purposes of appeal.

Respectfully submitted,

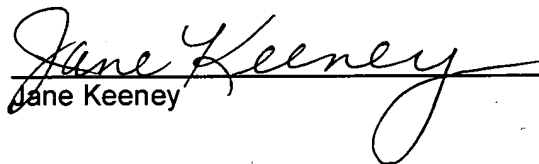
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